

## **CLAIMS:**

### **What is claimed is:**

1. A chewing gum composition for systemic, oral administration of an active,  
5 said composition comprising:

- a) an active;
- b) a gum base matrix, said gum base matrix comprising at least one substantially hydrophilic polymer; and
- c) a buffer system, whereby said active is administered by the chewing gum  
10 composition in a bi-phasic manner.

2. The composition of Claim 1, wherein said active is nicotine and wherein  
said composition provides for at least about 25% release of nicotine content within  
about 5 minutes after the onset of chewing.  
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3. The composition of Claim 2, wherein said composition provides for at least  
about 25% release of nicotine within about 3 minutes after the onset of chewing.

4. The composition of Claim 2, wherein said nicotine is in the form of at least  
20 one member selected from the group consisting of nicotine polacrilex and the  
pharmaceutically acceptable salts of nicotine.

5. The composition of Claim 4, wherein said nicotine comprises at least one  
member selected from the group consisting of nicotine hydrogen tartrate and  
25 nicotine bitartrate.

6. The composition of Claim 2 wherein said gum base matrix comprises  
polyvinylacetate and at least one other polymer member selected from the group  
consisting of water-insoluble, natural and synthetic elastomers, polymers and  
30 rubbers.

7. The composition of Claim 6, wherein said other polymer member is at

least one member selected from the group consisting of butadiene-styrene copolymers, butyl rubber, polyethylene, polyisobutylene and other polyvinylesters.

8. The composition of Claim 7, wherein said gum base matrix comprises polyvinylacetate, said polyvinylacetate having a molecular weight within the range of about 12,000 to 45,000, and further wherein said matrix is substantially free of butyl-rubber.

9. The composition of Claim 8, wherein said nicotine is nicotine polacrilex.

10. The composition of Claim 6, wherein said gum base matrix further comprises butyl rubber and polyisobutylene, and wherein said polyvinylacetate has a molecular weight of about 12,000, said gum base matrix comprising less than about 70% of said composition.

11. The composition of Claim 10, wherein said polymers comprise about 25 - 75% of said gum base matrix.

12. The composition of Claim 11, wherein said polymers comprise about 50 - 60% of said gum base matrix, and said gum base matrix comprises about 50 - 60% of said composition.

13. The composition of Claim 12, wherein said nicotine is at least one member selected from the group consisting of nicotine hydrogen tartrate and nicotine bitartrate.

14. The composition of Claim 2 wherein said buffer system comprises at least one buffer material which is at least one member selected from the group consisting of sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate, dipotassium phosphate, and potassium citrate, and wherein said buffer system raises the pH inside the mouth to at least about 7.5 within about 5 minutes of chewing said composition.

15. The composition of Claim 12, wherein said buffer material is at least one member selected from the group consisting of potassium carbonate, potassium bicarbonate, sodium carbonate and sodium bicarbonate.

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16. The composition of Claim 15, further comprising at least one filler material which facilitates release and/or absorption of nicotine.

10 17. The composition of Claim 13, further comprising at least one bulk sweetener selected from the group consisting of mono-, di-, tri- and polysaccharides, and natural and synthetic non-saccharide-based sweeteners.

15 18. The composition of Claim 17, wherein said bulk sweetener is at least one member selected from the group consisting of sorbitol and xylitol.

19. The composition of Claim 14, wherein said composition is substantially liquid-free.

20 20. The composition of Claim 1, wherein said active is nicotine, and wherein said gum base matrix and said buffering agent are configured to rapidly achieve a pharmacologically effective concentration of nicotine in the bloodstream within about 5 minutes after chewing of the composition begins and also to keep the concentration of nicotine in the bloodstream at or near the pharmacologically effective concentration for at least 20 minutes after chewing begins.

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21. The composition of Claim 20, wherein said gum base matrix and said buffering agent are configured to rapidly achieve said pharmacologically effective concentration of nicotine in the bloodstream within about 3 minutes after chewing begins.

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22. A nicotine chewing gum composition having a nicotine release rate inside the mouth which is substantially independent of the chew rate, said composition

releasing at least about 25% of nicotine content within about 5 minutes of chewing and a sustained release thereafter such that up to at least about 80% nicotine content is released within about 30 minutes of chewing.

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